

Centers for Medicare & Medicaid Services, HHS

§ 493.1204

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[58 FR 5230, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to December 31, 2002.

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—(1) Follow the manufacturer's instructions for instrument or test system operation and test performance;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures or check calibration at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing;

(5) Perform and document applicable specialty and subspecialty control procedures as specified under § 493.1223;

(6) Perform and document that remedial action has been taken when prob-

lems or errors are identified as specified in § 493.1219; and

(7) Maintain records of all quality control activities for two years. Quality control records for immunohematology and blood and blood products must be maintained as specified in § 493.1221.

[57 FR 7163, Feb. 28, 1992, as amended at 58 FR 5230, Jan. 19, 1993]

§ 493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning December 31, 2002.

For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it:

(a) Meets all applicable quality control requirements specified in this subpart when using a standardized method, a method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), a manufacturer's product modified by the laboratory, or a device (instrument, kit or test system) not cleared by the FDA as meeting certain CLIA quality control requirements; or

(b) Follows manufacturer's instructions when using a device (instrument, kit, or test system) cleared by the FDA as meeting the CLIA requirements for quality control located at §§ 493.1215, 493.1217, and 493.1223, and applicable parts of §§ 493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with the requirements of §§ 493.1204, 493.1213, 493.1219, and 493.1221 and those parts of §§ 493.1205, 493.1211, and 493.1218 that are unique to the laboratory facility and cannot be met by following manufacturer's instructions.

[58 FR 5230, Jan. 19, 1993]

§ 493.1204 Standard; Facilities.

The laboratory must provide the space and environmental conditions necessary for conducting the services offered.